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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/287,884

04/07/1999

HAROLD J. WANEBO

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EXAMINER

ANDERSON, JAMES D

ART UNIT

PAPER NUMBER

1614

MAIL DATE

DELIVERY MODE

04/13/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Advisory Action Before the Filing of an Appeal Brief	Application No. 09/287,884	Applicant(s) WANEBO ET AL.	
	Examiner JAMES D. ANDERSON	Art Unit 1614	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 09 March 2009 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
- (a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ They raise the issue of new matter (see NOTE below);
- (c) ☒ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☒ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
- The status of the claim(s) is (or will be) as follows:
- Claim(s) allowed: 20-29,31-33 and 42-54.
- Claim(s) objected to: _____.
- Claim(s) rejected: 30.
- Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:
See Continuation Sheet.
12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

/Ardin Marschel/
 Supervisory Patent Examiner, Art Unit 1614

/James D Anderson/
 Examiner, Art Unit 1614

Continuation of 3. NOTE: The proposed amendment to claim 30 and newly added claim 55, if entered, would raise new issues under 35 U.S.C. 112, 2nd paragraph. The metes and bounds of proposed amounts of paclitaxel and C6-ceramide effective to induce at least a 50% growth inhibition of a tumor "comprising head and neck squamous carcinoma cells" or "comprising pancreatic cells" are not clear. For example, would the amounts required to induce 50% growth inhibition of head and neck squamous carcinoma cells differ from those required to induce at least 50% growth inhibition of pancreatic cells?.

Continuation of 11. does NOT place the application in condition for allowance because: the rejection of claim 30 is maintained for the reasons of record. Claim 30 recites a pharmaceutical composition comprising paclitaxel, C6-ceramide, and a pharmaceutically acceptable carrier. Applicants have amended claim 30 to recite that the combination is effective to induce at least a 50% growth inhibition of a tumor comprising head and neck squamous carcinoma cells. Applicants argue that the combinations of cited references (Jayadev et al. and Mycek et al. or Spencer et al. and Cai et al.) do not disclose that C6-ceramide inhibits the growth of head and neck squamous carcinoma cells as recited in claim 30. However, the Examiner respectfully submits that the cited prior art suggests and motivates one skilled in the art to formulate a composition comprising paclitaxel and C6-ceramide for the purpose of treating cancer. Applicants recitation of an intended use and effect of the claimed combination is not patentable over the cited prior art.

With regard to Applicant's arguments that they have demonstrated unexpected results, such arguments are persuasive with respect to the claimed methods of treating head and neck cancer or pancreatic cancer comprising administering paclitaxel and C6-ceramide in combination. However, such results are not demonstrative of an unexpected result with respect to pharmaceutical compositions comprising paclitaxel and C6-ceramide as recited in claim 30. The cited prior art suggests that such combinations would be effective to treat cancer. As such, Applicant's results are not commensurate in scope with the claims and do not demonstrate an unexpected result in light of the teachings of the cited prior art.